PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/06 — A1

(11) International Publication Number: **WO 00/66035**

(43) International Publication Date: 9 November 2000 (09.11.00)

(21) International Application Number: PCT/US00/08105

(22) International Filing Date: 27 March 2000 (27.03.00)

(30) Priority Data:
09/304,650 4 May 1999 (04.05.99) US

(71) Applicant: HEARTSTENT CORPORATION [US/US]; 7145 Boone Ave. N., Suite 150, Brooklyn Park, MN 55428 (US).

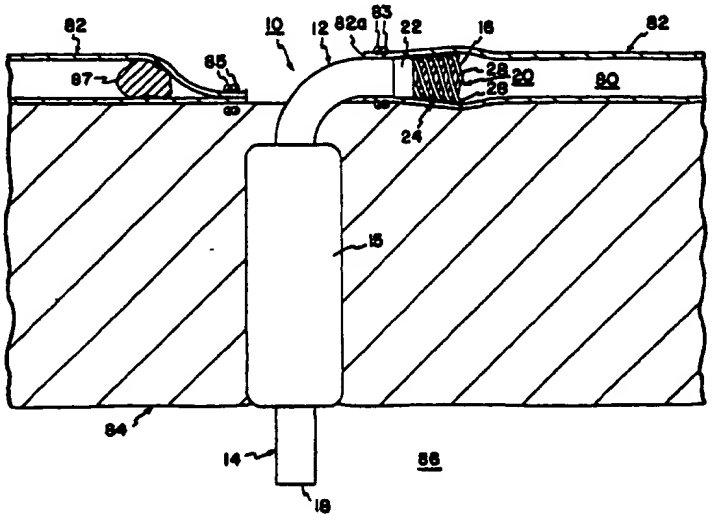
(72) Inventor: VANNEY, Guy, P.; 7489 Meadowwood Court, Brooklyn Park, MN 55444 (US).

(74) Agent: BRUESS, Steven, C.; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).

(81) Designated States: AE, AG, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, DZ, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (Utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: COMPLIANT TRANSMYOCARDIAL IMPLANT



(57) Abstract

A transmyocardial implant includes a hollow rigid conduit having a vessel portion and a myocardial portion. The vessel portion is sized to be inserted into a coronary vessel. The myocardial portion is sized to extend from the vessel portion and through a myocardium into a heart chamber. The conduit has open vessel and myocardial ends on respective ones of the vessel and myocardial portions to define a blood flow pathway within an interior of the conduit between the vessel and myocardial ends. The myocardial portion is formed of a conduit material sufficiently rigid to resist deformation and closure of the pathway in response to contraction of the myocardium. The vessel portion has a radial compliance approximating a radial compliance of the vessel.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

COMPLIANT TRANSMYOCARDIAL IMPLANT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to an implant for passing blood flow directly between a chamber of the heart and a coronary vessel. More particularly, this invention pertains to such an implant with an enhanced design for enhanced compliance of a transmyocardial conduit in a coronary vessel.

2. Description of the Prior Art

Commonly assigned U.S. Patent No. 5,755,682 and PCT International Publication No. WO 98/06356 teach an implant for defining a blood flow conduit directly from a chamber of the heart to a lumen of a coronary vessel. An embodiment disclosed in the aforementioned patent and application teaches an L-shaped implant. The implant is a conduit having one leg sized to be received within a lumen of a coronary artery and a second leg sized to pass through the myocardium and extend into the left ventricle of the heart. As disclosed in the above-referenced patent and application, the conduit remains open for blood flow to pass through the conduit during both systole and diastole. The conduit penetrates into the left ventricle in order to prevent tissue growth and occlusions over an opening of the conduit.

Commonly assigned and co-pending U.S. patent application Serial No. 08/944,313 filed October 6, 1997, entitled "Transmyocardial Implant", and filed in the name of inventors Katherine S. Tweden, Guy P. Vanney and Thomas L. Odland, teaches an implant such as that shown in the aforementioned '682 patent with an enhanced fixation structure. The enhanced fixation structure includes a fabric surrounding at least a portion of the conduit to facilitate tissue growth on the exterior of the implant. This application has the same disclosure as PCT/US 98/17310.

Implants such as those shown in the aforementioned patent and applications include a portion to be placed within a coronary vessel and a portion to be placed within the myocardium. When placing a portion of the implant in the coronary vessel, the vessel is incised a length sufficient to insert the implant. When placed within the coronary vessel, the implant discharges flow axially into the vessel.

When placing an implant, a portion of the coronary artery is dissected. The dissected portion is incised and the vessel portion of the implant is inserted into the lumen. A stay suture secures the artery to the implant. The stay suture is paced around the artery and vessel portion a distanced spaced from the open end of the vessel portion.

The implant is rigid. The vessel is compliant. Since the vessel is radially flexing over time, the compliance mismatch between the vessel portion and the vessel may damage the vessel.

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a transmyocardial implant is disclosed for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel. The implant includes a hollow rigid conduit having a vessel portion and a myocardial portion. The vessel portion is sized to be inserted into the vessel. The myocardial portion is sized to extend from the vessel portion and through the myocardium into the chamber. The conduit has open vessel and myocardial ends on respective ones of the vessel and myocardial portions to define a blood flow pathway within an interior of the conduit between the vessel and myocardial ends. The myocardial portion is formed of a conduit material sufficiently rigid to resist deformation and closure of the pathway in response to contraction of the myocardium. The vessel portion has a radial compliance approximating a radial compliance of the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation view of a transmyocardial conduit according to the present invention and showing a myocardial portion of the implant placed through a heart wall and with a vessel portion placed in a coronary vessel; and

Fig. 2 is a side sectional view of a vessel portion of the conduit of Fig. 1 placed in a coronary vessel with a coiled end of the vessel portion held in a constricted state.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With initial reference to Fig. 1, a transmyocardial conduit 10 is shown in the form of an L-shaped rigid tube. In the preferred embodiment described below, the conduit 10 is titanium but may be any other rigid biocompatible material such as pyrolytic carbon or may be titanium coated with pyrolytic carbon. The material of

the conduit 10 is preferably a rigid material in order to withstand contraction forces of the myocardium. By way of example, the tube will have an outside diameter of about 2.5 millimeters and an internal diameter of about 2.0 millimeters to provide a wall thickness of about .25 millimeters.

The conduit 10 has a first or vessel portion 12 sized to be received within the lumen of a coronary vessel such as the lumen 80 of a coronary artery 82. The conduit 10 has a second or myocardial portion 14 extending at an angle to the axis of portion 12. The myocardial portion 14 is sized to extend from the coronary artery 82 directly through the myocardium (heart wall) 84 and protrude into the left ventricle 86 of a patient's heart.

The vessel portion 12 has a vessel opening 16. The myocardial portion 14 has a myocardial opening 18 in communication with an interior 19 (shown in Fig. 2) of the implant 10. Therefore, blood can freely flow through the conduit 10 between the left ventricle 86 and the lumen 80 of the coronary artery 82. Blood flows axially out of opening 16 parallel with the axis of lumen 80.

As discussed more fully in the afore–mentioned commonly assigned and co–pending U.S. Patent Application Serial No. 08/944,313, the myocardial portion 14 may be provided with a tissue–growth inducing material such as a polyester sleeve 15 to immobilize the implant 10 within the myocardium 84.

At least a distal portion of the vessel portion 12 is a compliant structure 20. In the embodiment shown, the compliant structure 20 includes a tubular member 22 connected to a radially flexible coil 24. As shown in Fig. 2, the vessel portion 12 includes an annular groove 26. The tubular member 22 slips or is press–fit into the groove 26.

The coil 24 is preferably four individual coils 28 extending from the tubular member in a cantilevered fashion at 90° spacings about the circumference of the tubular member 22. The individual coils 28 expand for the coil 24 to assume a conical shape (shown in Fig. 1) with a narrow end at the tubular member 22. At the opening 16, the coil 24 expands to a diameter about .75 mm larger than the coil's narrow diameter. Alternatives to coils 28 include axially extending fingers which expand radially outwardly and lattice structured stents.

To facilitate placement in a vessel 82, a sleeve 32 of thin tear–away plastic with a handle 34 surrounds the coil 24. The sleeve 32 compresses the coil 24 from the conical shape of Fig. 1 to a cylindrical shape illustrated in Fig. 2.

A surgeon dissects a portion of the artery 82 away from the myocardium 84. The surgeon legates the artery 82 distal to an obstruction 87 with sutures 85. The surgeon then forms an incision through the artery 82 distal to the legating suture 85. The coil 24 (compressed by sleeve 32) is slipped into the lumen 80 through the open end 82a of the artery 82. A stay suture 83 is placed around the vessel 82 over the vessel portion 12. A surgical procedure for placing an implant and tools for such procedure are more fully described in commonly assigned and co-pending U.S. patent application Ser. No. 09/179,711 filed October 27, 1998.

After positioning the implant as shown in Fig. 2, the sleeve 32 is peeled away by pulling on handle 34 permitting the coil 24 to expand. The expansion causes a corresponding expansion of the lumen 80 at the incised artery end 82a (Fig. 1). The amount of enlargement of the artery 82 is a function of the natural swelling of the artery. More specifically, the coil 24 is flexible and is radially compressible to compress and expand in response to compression and expansion of the artery 82. According, the compliance of the vessel portion 12 now more closely matches a compliance of the artery. The compliance matching is achieved by material selection and geometry of the individual coils 28 for the coil 24 to have a compliance approximating arterial compliance. Such compliance is about $10x10^{-2}$ % radial change per 1 mmHg.

From the foregoing, the invention has been described in a preferred embodiment. Modifications and equivalents of the disclosed concepts are intended to be included within the scope of the claims.

What is claimed is:

1. A transmyocardial implant for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel, said implant comprising:

a hollow rigid conduit having a vessel portion and a myocardial portion, said vessel portion sized to be inserted into said vessel, said myocardial portion sized to extend from the vessel portion and through said myocardium into said chamber;

said conduit having open vessel and myocardial ends on respective ones of said vessel and myocardial portions to define a blood flow pathway within an interior of said conduit between said vessel and myocardial ends;

said myocardial portion of said conduit formed of a conduit material sufficiently rigid to resist deformation and closure of said pathway in response to contraction of said myocardium;

at least a portion of said vessel portion having a radial compliance approximating a radial compliance of said vessel.

2. An implant according to claim 1 wherein said portion of said vessel portion is an open construction flexible member.

3. An implant according to claim 1 wherein said portion of said vessel portion is radially compressible.

4. An implant according to claim 3 further comprising a removable sleeve for holding said portion of said vessel portion is a radially compressed state until after placement of said vessel portion in said artery with said sleeve removable thereafter for said vessel portion to radially expand and contract in response to expansion and contraction of said vessel.

5. An implant according to claim 1 wherein said portion of said vessel portion is a coil.

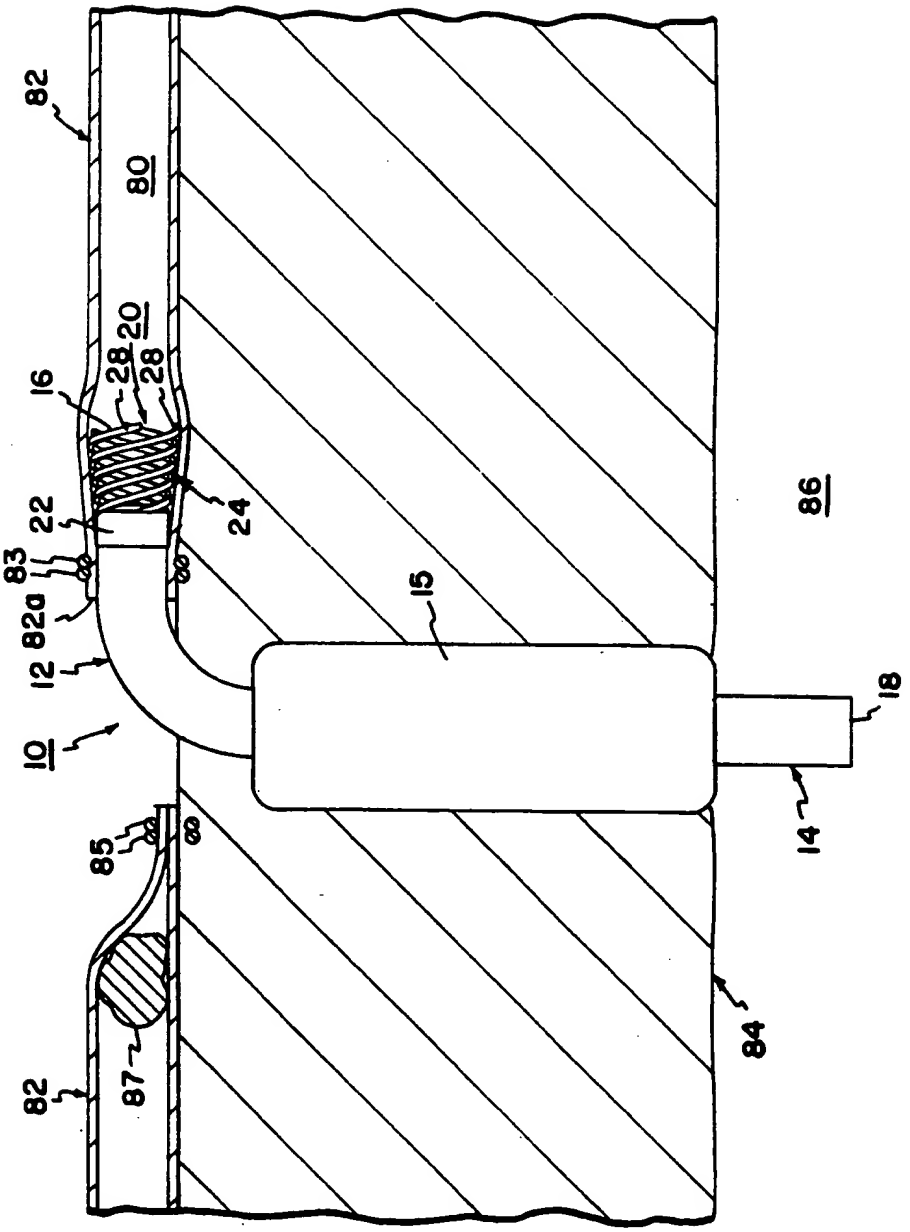


FIG. 1

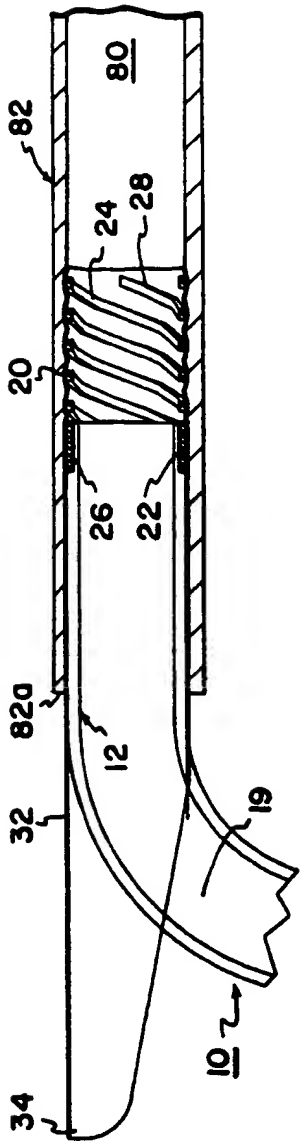


FIG. 2

INTERNATIONAL SEARCH REPORT

In ..national Application No
PCT/US 00/08105

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 99 40868 A (VENTRICA INC) 19 August 1999 (1999-08-19) page 36, line 3 - line 16; figure 37	1,3
E	US 6 053 942 A (HARRISON DONALD C ET AL) 25 April 2000 (2000-04-25) claims; figures	1-3
A	WO 98 46115 A (TRANSVASCULAR INC) 22 October 1998 (1998-10-22) figure 8A; example 8	1-3
A	WO 98 06356 A (HEARTSTENT LLC) 19 February 1998 (1998-02-19) cited in the application the whole document	1-3

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July 2000	20/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/08105

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 300 244 A (BOKROS JACK C) 17 November 1981 (1981-11-17) figures ---	2,3,5

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/08105

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9940868 A	19-08-1999	AU 2674699 A	30-08-1999
US 6053942 A	25-04-2000	NONE	
WO 9846115 A	22-10-1998	AU 6968698 A	11-11-1998
		EP 0981295 A	01-03-2000
WO 9806356 A	19-02-1998	US 5755682 A	26-05-1998
		US 5944019 A	31-08-1999
		AU 716771 B	09-03-2000
		AU 4057397 A	06-03-1998
		DE 19735141 A	30-04-1998
		EP 0959815 A	01-12-1999
		GB 2316322 A,B	25-02-1998
		JP 2886847 B	26-04-1999
		JP 10146350 A	02-06-1998
		NO 990688 A	12-04-1999
US 4300244 A	17-11-1981	NONE	